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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Steen Meier Ronborg

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EXAMINER

WITCZAK, CATHERINE

ART UNIT

PAPER NUMBER

3767

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/558,943	Applicant(s) RONBORG ET AL.	
	Examiner CATHERINE N. WITCZAK	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/14/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The terms “distal” and “proximal” in claims 1, 3, 4, 7-9, 20, and 22 are used by the claim to mean “proximal” and “distal”, while the accepted meaning is “distal – situated farthest from” and “proximal – closest to.” The terms are indefinite because the specification does not clearly redefine the term.

2. Claim 1 recites the limitation "said medicament or said diagnostic agent" in line 2. There is insufficient antecedent basis for this limitation in the claim.
3. Claim 26 recites the limitation "the labeling means" in line 2. There is insufficient antecedent basis for this limitation in the claim. For the sake of examination, it has been assumed that claim 26 is dependent on claim 25 which recites “a labeling means.”

Claim Objections

4. Claim 1 is objected to because of the following informalities: "slided" in line 16 should be changed to "slid". Appropriate correction is required.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, a) a device having a first sealing, second sealing and a removable rod house sealing as specified by claims 1 and 3; b) a device having a rod having at least two proximal end as per claim 20; and c) a rod house comprising at least two rod connected at their distal ends to a common activation means as per claims 21 and 22 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Truesdale (US 4,990,135).

Truesdale discloses a rod house (54) in which a rod (52) having a distal end and a needle (16) having a tapering end with a recess (Figure 5b) is slidably disposed; a chamber house (12) connected (via 56/58) to the rod house; the chamber house comprising at least one chamber, where a first wall of the chamber is a first sealing (28) and a second wall is a second sealing (60); the chamber comprising a medicament; the rod penetrating the first and second sealing when slid proximally; the rod house being sealed by a removable rod house sealing (see Figure 2, wherein sealing 60 acts as a removable end seal for the rod house when the rod house and chamber house are attached); the distal end of the rod projecting out the distal end of the rod house (Figure 2); a spring (112) for retracting the rod after activation; a shoulder (76) in the house which engages a shoulder (106) on the rod for stopping advancement of the rod; the chamber house made from a plastic (Lucite); and a marking means (106) disposed concentrically on the rod which is activated when the rod is activated to mark that the rod has been activated (in that the user can gauge the movement of 106 relative to 76).

6. Claims 1, 2, 4, 6-8, 15, 17, 18, 20, 21, 23, 24 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiley et al (US 5,104,620).

Wiley et al disclose a rod house (16) in which a rod (32) having a distal end and a needle (32) having a tapering end is slidably disposed; a chamber house (50) connected to the rod house; the chamber house comprising at least one chamber, where a first wall of the chamber is a first sealing (12) and a second wall is a second sealing (16); the chamber comprising an allergen (22); the rod penetrating the first and second sealing when slid proximally; the distal end of the rod projecting out the distal end of the

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rod house (Figure 2); the chamber house made from a plastic (Lucite); and a marking means (36) disposed concentrically on the rod which is activated when the rod is activated to mark that the rod has been activated; the rod hose comprising at least two rods and the device comprising at least two chamber houses.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 22, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiley et al as modified by Fishman et al (US 5,076,282).

As to claim 22, Wiley et al disclose the claimed invention except for the device having a common activation means for a allergy testing device having a plurality of rods. Fishman et al teach in Figure 30 that it is known to use a common actuator (536) for a allergy device comprising multiple piercing members. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Wiley et al with the teaching of Fishman et al since such a modification would simplify and expedite the use of the device of Wiley et al by allowing the user to actuate all the piercing members in one step.

As to claims 25 and 26 Wiley et al disclose the claimed invention except for the device having a labeling means arranged on the chamber house. Fishman et al teach in Figure 46 that it is known to use a marking device (570) on the bottom surface of an allergy testing unit. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Wiley et al with the teaching of Fishman et al since such a modification would give the user indication of where the

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test was performed so as to make the process of identifying a patients reaction to an allergen easier to perform.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Catherine N Witczak/
Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767